

UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois
corporation,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC., a
Delaware corporation,

Defendant.

Case No. CV-07-00250***

Magistrate Judge Mary Pat Thyng

PROPOSED DATES FOR SCHEDULING ORDER

Pursuant to this Court's June 1, 2007 Order, counsel for Abbott Laboratories ("Abbott") and counsel for Teva Pharmaceuticals USA, Inc. ("Teva") respectfully submit the following proposal relating to scheduling for this matter.¹

A. Nature of the Case

This is a patent infringement case arising under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2). Abbott markets a prescription medication known as DEPAKOTE® ER (extended-release), which has been approved by FDA for treatment of epilepsy, bipolar disorder, and prophylaxis of migraine headaches. Abbott owns certain patents, including U.S. Patent No. 6,419,953 ("the '953 patent"), that are listed in the FDA's "Orange Book" in conjunction with DEPAKOTE® ER. The '953 patent covers a formulation for achieving the extended release of a drug product over time, and the patent expires December 18, 2018.

Teva has filed Abbreviated New Drug Application No. 78-700 (the "ANDA"), seeking

¹ For convenience and ease of reading, the parties have submitted a single, condensed proposal rather than submitting two full-length versions of this Court's Draft Scheduling Order. However, the parties will provide a complete proposed scheduling order once the Court determines what dates are appropriate for this case going forward.

FDA approval of a proposed generic version of DEPAKOTE[®] ER. In the ANDA, Teva included a certification (known as a Paragraph IV Certification) stating that its proposed product, if allowed on the market, would not infringe any valid claim of, among other things, the '953 patent. Thus, Teva seeks approval to market its product prior to the expiry of that patent.

As required by statute, Teva provided notice to Abbott about the filing of the ANDA and the Paragraph IV Certification. Within 45 days of receiving that notice, Abbott filed this action, alleging that Teva's proposed generic product would, if allowed on the market, infringe the '953 patent. As a result of Abbott's timely filing, there is currently in place a statutory stay that will prevent FDA approval of the ANDA for a period of 30 months (until September 2009), absent some earlier resolution of this matter on the merits. Teva has answered the complaint, denying infringement, and has asserted a counterclaim seeking a declaratory judgment that its proposed product does not infringe any claim of the '953 patent.

B. Agreed Matters

Counsel for the parties have conferred and agree that 70 hours per side for depositions should be sufficient.² If there is a need to expand this time allotment as the case progresses, the parties will work together in good faith to address the issue.

C. Contested Matters

The parties were unable to agree on a joint schedule for pretrial and trial activities. The primary areas of dispute are (i) the appropriate length of time to trial; (ii) the allocation of time at trial; and (iii) whether there should be a separate claim construction process undertaken during the fact discovery period and before summary judgment (Teva advocates such a procedure, but Abbott disagrees). The parties' respective proposed schedules are set forth below.

² Time consumed by the party in actual questioning of the witness shall count against that party's time, regardless of which party noticed the deposition.

Abbott's Proposal

Abbott believes that a trial date cannot be set within 18 months of the filing of this complaint, as suggested by Local Rule 16.2(c), and asks this Court to so certify. This is a complex scientific dispute that will almost certainly revolve around the testimony of experts for both sides relating to pharmaceutical formulation. Particularly in light of the current constraints on this Court (there is currently no district judge even assigned to this case), Abbott does not believe that trial within 18 months (much less the shorter period advocated by Teva) is reasonable. In addition, this Court's Draft Scheduling Order anticipates certain additional procedures, including a tutorial on the technology involved in the patent and separate claims construction briefing, that must be accounted for in determining time to trial. For all of these reasons, Abbott believes that it would be appropriate to schedule trial approximately 24 months from the filing of this case.

In terms of the ordering of proceedings, Abbott respectfully submits that the most appropriate course would be to conduct the claim construction inquiry after discovery has been completed. This can be accomplished as part of the summary judgment proceedings, as this Court's Draft Scheduling order suggests. Abbott cannot agree to Teva's proposal that claim construction be resolved during the fact-discovery phase because, among other things, it would require the parties to undertake two separate rounds of expert discovery (with reports and depositions relating to claim construction at one stage, followed by more reports and more depositions relating to infringement later). In Abbott's view, this would increase the burden on both sides, and the Court, without any significant increase in efficiency. With this in mind, Abbott proposes the following schedule:

Proposed Date	Event
6.25.07	Initial 26(a)(1) Disclosures
7.2.07	Deadline to Submit a Stipulated Protective Order
1.7.08	Deadline to Amend the Pleadings or Join Additional Parties
	Interim Status Report Due
1.14.08	Status Conference at 1:00 p.m. EDT
5.1.08	Close of Fact Discovery
6.2.08	Expert Reports Due - Burden of Proof
7.1.08	Responsive Expert Reports
8.8.08	Close of Expert Discovery
9.4.08	Tutorial Describing Technology & Matters at Issue Due
9.19.08	Comment to Opposing Party's Tutorial Due
10.10.08	Parties Exchange Proposed Claims Constructions
10.31.08	Parties Submit a Joint Claim Construction Chart
11.21.08	Parties' Individual Briefs on Claim Construction Due
12.22.08	Parties' Responsive Briefs on Claim Construction Due
	Dispositive Motion Deadline
1.26.09	Deadline for any <i>Daubert</i> Challenges to Expert Testimony
2.9.09	Responses to Dispositive Motions Due
2.17.09	Replies in Support of Dispositive Motions Due
3.9.09	Hearing on Claim Construction and Summary Judgment
4.30.09	Final Pretrial Order (Including Motions <i>in Limine</i>) Due
5.11.09	Final Pretrial Conference
6.1.09	Trial (lasting 7 to 10 days, with plaintiff allocated 50-60% of the total trial time in which to present its case, and the remaining time allocated to defendant's case)

Teva's Proposal

Teva believes that, in conformity with Local Rule 16.2(c), a trial date should be set within 18 months of the filing of this complaint. Teva has narrowed the issues in dispute substantially. Only one (1) patent, with only six (6) independent claims, is at issue, as Teva has not asserted declaratory judgment claims as to related Abbott Orange Book patents that Abbott did not assert. Further, Teva has not raised issues of invalidity. Consequently, the only issue left in this litigation is that of infringement. Because Teva has not launched a commercial product, the question of infringement is a question of infringement of Teva's ANDA under Section 271(e) of the Patent Code. Teva provided Abbott with pertinent portions of the ANDA prior to this institution of this litigation -- little discovery will be necessary. While each side no doubt will present expert testimony on the infringement issue, the existence of a small number of experts does not justify extending the presumptive time for trial under Local Rule 16.2(c).

Teva also submits that the claim construction proceedings should be scheduled towards the end of general discovery and before the onset of expert discovery. As the Court is aware, claim construction is a matter of law for the Court, which may or may not agree with proposals submitted by the parties. This claim construction will define the metes and bounds of the patent claims that then will be the basis for the infringement analysis. It is prudent to leave a small period of general discovery after the Court issues its claim construction ruling in the event that the constructions require the parties to seek additional information. Teva further submits that it is prudent to sequence the case so that the claim construction issues before expert discovery begins. Otherwise, the experts would need to opine on infringement issues based on assumptions as to the ultimate constructions -- no doubt, some of these will turn out to be incorrect and

supplemental discovery will be necessary. It is cleaner and more efficient for the parties and the Court to define the scope of the intellectual property rights before expert discovery.

Teva proposes the following schedule for discovery, motion practice, and trial in this case:

Proposed Date	Event
June 25, 2007	Initial 26(a)(1) Disclosures
July 2, 2007	Deadline to Submit a Stipulated Protective Order
August 8, 2007	Deadline to Amend the Pleadings or Join Additional Parties
September 4, 2007	Interim Status Report Due
September 7, 2007	Parties Exchange Proposed Claims Constructions
September 14, 2007	Parties Submit a Joint Claim Construction Chart
October 2, 2007	Parties' Individual Briefs on Claim Construction Due
November 1, 2007	Parties' Responsive Briefs on Claim Construction Due
October 8, 2007 through October 19, 2007.	Depositions Limited to Expert Material Submitted with Claim Construction Briefing (if any)
November 15, 2007	Tutorial Describing Technology & Matters at Issue Due
November 26, 2007	Comment to Opposing Party's Tutorial Due
November 28, 2007	Status Conference at 10:00 a.m. EDT
30 days after the issuance of the Court's Claim Construction Order.	Close of Fact Discovery
60 days after the issuance of the Court's Claim Construction Order	Expert Reports Due - Burden of Proof

Proposed Date	Event
90 days after the issuance of the Court's Claim Construction Order.	Responsive Expert Reports
120 days after the issuance of the Court's Claim Construction Order.	Close of Expert Discovery
150 days after the issuance of the Court's Claim Construction Order	Dispositive Motion Deadline Deadline for any <i>Daubert</i> Challenges to Expert Testimony
November 15, 2007	Hearing on Claim Construction and Summary Judgment
See Local Rules	Responses to Dispositive Motions Due
See Local Rules	Replies in Support of Dispositive Motions Due
October 15, 2008	Final Pretrial Order (Including Motions <i>in Limine</i>) Due
October 22, 2008	Final Pretrial Conference
October 29, 2008	Trial – 7 days – 24 hours each (<i>7 days at 7 hours each (9-5 with an hour for lunch), divided by 2 = 24.5. Rounded down to allow for unforeseen delays</i>).

Dated: June 8, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 8, 2007, a true and correct copy of the foregoing **Proposed Dates for Scheduling Order** was caused to be served on the following via CM/ECF filing and electronic mail:

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